

Message Text

UNCLASSIFIED

PAGE 01 STATE 071218
ORIGIN HEW-06

INFO OCT-01 AF-10 ISO-00 ARA-14 EUR-12 EA-12 OES-07
SIG-03 EB-08 COME-00 /073 R

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APPROVED BY: OES/ENP: EN: WJWALSH III
DHEW/PHS/OASH:OIH: REVANS
EA/ANP: WGALLAGHER (INFO)
EUR/WE: BMCINLEY (INFO)
AF/S: JTAYLOR (INFO)
EA/ANP: TWAJDA (INFO)
EUR/WE: JDOBBINS (INFO)
EUR/NE: WNEWLIN (INFO)
-----069712 211203Z /11/42

R 202026Z MAR 78
FM SECSTATE WASHDC
TO AMEMBASSY WELLINGTON
AMEMBASSY CANBERRA
AMEMBASSY MEXICO
AMEMBASSY PARIS
AMEMBASSY BRUSSELS
AMEMBASSY ROME
AMEMBASSY PRETORIA

UNCLAS STATE 071218

C O R R E C T E D C O P Y - FOR ADDRESSEE

E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, NZ, AS, MX, FR, BE, SF, IT

SUBJECT:FDA ADVISORY - POTENTIAL FIRE HAZARD IN NEBULIZER
FOR RESPIRATORY THERAPY. (RECALL T-052-3)

1. FDA ADVISES OF THE FOLLOWING RECALL:
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PAGE 02 STATE 071218

PRODUCT INVOLVED - THE PRODUCTS INVOLVED IN THIS RECALL ARE
"MAXICOOL" AND "HYDRO-SHPERE" NEBULIZERS USED FOR RESPIRA-
TORY THERAPY IN HOSPITALS.
PRODUCT IDENTIFICATION - THE NEBULIZERS INVOLVED IN THIS
RECALL ARE PRODUCED BY MCGAW RESPIRATORY THERAPY, IRVINE,
CA. UNDER THE NAMES "MAXI-COOL" AND "HYDRO-SPHERE". THE
SPECIFIC UNITS INVOLVED ARE THOSE WITH METAL COMPONENTS IN

THE INTERIOR PORTION OF THE MANIFOLDS WHICH ARE INSERTED,
SCREWED INTO, THE OUTER CONTAINER.
MANUFACTURER/RECALLING FIRM - MCGAW RESPIRATORY THERAPY,
16812 MILLIKEN AVE., IRVIE, CALIFORNIA.

2. REASON FOR RECALL RECOMMENDATION - THE PRODUCT HAS BEEN
IMPLICATED IN TWO HOSPITAL FIRES IN THE "RESPIRATORY THERAPY"
ROOMS. THE FIRM INVESTIGATED THE FIRES AND WHILE NOT
DEFINITELY DETERMINING THE CAUSE THEY DID DETERMINE THAT
THE POTENTIAL FOR IGNITION DID EXIST WITHIN THE DEVICE
GIVEN ANY CONATMINATION OF THE HOSPITAL'S OXYGEN SUPPLY.

IN ANY NEBULIZER A POTENTIAL FOR STATIC ELECTRICITY EXISTS
WITH THE MIST ASSUMING A POSITIVE CHARGE AND THE WATER
ASSUMING A NEGATIVE CHARGE. IN THE NEBULIZERS UNDER
"RECALL" (ACTUALLY A FIELD CORRECTION" THERE ARE SOME
STAINLESS STEEL PARTS USED IN THE MANIFOLD LOCATED IN THE
INTERIOR OF THE MACHINE WHICH CREATE THE POTENTIAL FOR
"SPARKING" OF THE ELECTRICAL CHARGE BUILT-UP. (THE NEBU-
LIZERS NOT UNDER RECALL AND THOSE RETROFITTED HAVE ALL
PLASTIC INTERIOR PORTIONS OF THE MANIFOLD WICH ESSENTIALLY
ELIMINATES THIS POTENTIAL FOR SPARKS).

3. ACTION - POSTS ARE REQUESTED TO CONTACT FOREIGN
CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED ADVISORY FROM
FIRM REQUESTING "NOT TO USE SUBJECT UNITS UNTIL THEY ARE
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PAGE 03 STATE 071218

RETROFITTED WITH THE NEW MANIFOLD WITH QUALIFICATION THAT
IN EVENT OF EMERGENCY THE PRODUCT COULD BE USED WITH
COMPRESSED AIR BUT NOT OXYGEN." DEALERS PRESUMED TO
HAVE BEEN SENT REPLACEMENT MANIFOLDS AND TECHNICAL BULLETINS
WITH INSTRUCTIONS TO CONTACT MCGAW WITH REGARD TO QUESTIONS
OR FOR ASSISTANCE, IF NECESSARY.

4. FOREIGN CONSIGNEES AS FOLLOWS:
MCGAW ETHICALS LTD., P.O. BOX 18-069, AUCKLAND 6, NEW
ZEALAND

AHS/AUSTRALIA PTY LTD., P.O. BOX 371, EPPING NSW 2121,
AUSTRALIA HOSP.

DEL SAGRADO CORAZON, TIJUANA, MEXICO

AMERICAN HOSP. CUPPLY, MISSISSAUGA, ONTARIO, CANADA

AHS FRANCE, BOITE, POSTALE 716, 95004 CERGY, FRANCE

VANDER HYDEN, RUE DU MARIAS, 1000 BRUXELLES, BELGIUM

AHS SOUTH AFRICA, P.O. BOX 2726, JOHANNESBURG, S. AFRICA

POCHTECA INTERNACIONAL, MEXICO CITY, MEXICO

FLETES AEREAS DE MEXICO, AEROPUERTO INTERNACIONAL, MEXICO
CITY LABORATORI DON BAXTER SPA, 122/124 VIA FLAVIA, TRIESTE
ITALY. VANCE

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
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Copy: SINGLE
Draft Date: 20 mar 1978
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Decaption Note:
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Disposition Approved on Date:
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TAGS: OGEN, ETRD, EIND, TBIO, NZ, AS, MX, FR, BE, SF, IT
To: WELLINGTON CANBERRA MULTIPLE
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Review Markings:
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